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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,544	09/10/2003	Hidenobu Senpuku	242617US0	3249

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EXAMINER

GRUN, JAMES LESLIE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/658,544	Applicant(s) SENPUKU ET AL.	
	Examiner James L. Grun	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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The disclosure is objected to because of the following informalities: the specification is replete with grammatical, idiomatic, and spelling errors too numerous to be specifically listed and should be carefully revised. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant teaches that determining the quantity of *Streptococcus mutans* in human saliva does not correlate with caries risk for a number of reasons (see e.g. pages 2-3). Yet, determining the quantity of *Streptococcus mutans* in human saliva at a single time point is the only measure put forth in the instant specification for correlating the level of IgA antibodies to caries risk. In this regard, Matsushita et al. (Inf. Imm. 62: 4034, 1994) determined the level of antibody

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responses to a recombinantly produced (r) surface protein antigen of *Streptococcus mutans* (PAc) in the serum and saliva of human patients, yet all the patients were naturally infected with *mutans* streptococci (page 4036). Since any correlative relationship between IgA antibodies at a single time point and caries risk is purely speculative and unpredictable according to applicant's own teachings, one would question applicant's possession of the invention as disclosed and/or claimed and one not be assured of the ability to practice the invention as disclosed and/or claimed absent further written description and guidance from applicant.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is a method claim and, as such, it should clearly set forth the various method steps in a positive, sequential manner using active tense verbs such as mixing, reacting, and detecting. Terms such as "employing" or "using" are not valid method steps. Method claims should also conclude with a step relating the method result to the purpose of the method, preferably to the purpose as also set forth in the preamble of the claim. It is not clear what is included or excluded from the claim because it is not clear if open or closed claim language is intended. Moreover, it is not clear what is included in the claim because Formula 1 follows the period ending the claim. The assigned "SEQ ID NO:" identifier must be used to reference a listed sequence, even if the sequence is embedded in the claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Matsushita et al. (Inf. Imm. 62: 4034, 1994) in light of the instant disclosure.

Matsushita et al. determined IgA antibodies specific for a recombinantly produced (r) surface protein antigen of *Streptococcus mutans* (PAc) in the saliva of humans (see e.g. Fig. 2B). Inherently, the rPAc has the sequence as instantly claimed (amino acid residues 361-386) in the A-region therein (amino acid residues 219-464). Moreover, the reference determined linear epitopes in the A-region of PAc which bound the salivary IgA antibodies (see Fig. 4). The reference teaches that human sera reacted with the peptide consisting of amino acid residues 363-373 of PAc (see Fig. 3 and page 4040) and that antibodies in saliva were similar in reactivity to those found in the serum of the same donor (see Figs. 3 and 4; and, page 4037).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Okahashi et al. (Inf. Imm. 61: 1301, 1993) determined linear epitopes in the A-region of PAc which bound antibodies elicited in immunized mice.

Senpuku et al. (Immunol. 95: 322, 1998) identified peptides of PAc which bound to various human major histocompatibility complex class II molecules.

Koga et al. (US 5,352,450) teach the sequence of PAc.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

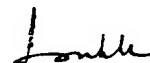
The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James L. Grun, Ph.D.
September 14, 2006



LONG V. LE 09/14/06
SUPERVISORY PATENT EXAMINER
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